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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,792	07/23/2003	Marc A. Mandro	1062/D78	9009

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BROMBERG & SUNSTEIN LLP
125 SUMMER STREET
BOSTON, MA 02110-1618

EXAMINER

LEE, PATRICK J

ART UNIT	PAPER NUMBER
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2878

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/625,792

Applicant(s)

MANDRO ET AL.

Examiner

Patrick J. Lee

Art Unit

2878

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. This action is in response to amendment filed December 12, 2005.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,645,177 B1 to Shearn.

Shearn discloses a syringe driver system comprising a syringe (30), syringe body (32), shaft (56), stopper (44), lead screw (54), and plunger (42).

With respect to claims 1, 12, & 17, Shearn discloses a plunger (42) as a plunger rod coupled to stopper (44) as a piston. Plunger (42) on arm (56) discloses a series of

marks (58) as an encoded pattern of encoding features. Shearn discloses an optoelectronic detector (74) that includes a light source and a light detector for detecting marks (58). Shearn finally discloses a processor to determine position of the plunger at a near-end-of-infusion point (as a fiducial reference position) and an end of infusion point (see column 8, lines 20-32). While this may not explicitly disclose the displacement, such would have been obvious to one of ordinary skill in the art as it would allow for accurate determination of positioning and accurate determination of the liquid volume in the syringe.

With respect to claims 2-3 & 13, the modified Shearn does not explicitly disclose the use of modulated optical transmission or reflection, but such would have been obvious to one of ordinary skill in the art because this would have allowed for a clear definition of position by providing areas of different light sensing.

With respect to claims 4, 13, & 18, the modified Shearn discloses the optical detector (74) to sense encoding features (58) as regions of modulated optical transmissions through plunger rod (42).

With respect to claims 5 & 15, the modified Shearn illustrates the marks (58) being located at different distances.

With respect to claims 6-9, 16, & 19, the modified Shearn discloses the size of markers (58) being detected by switch (74) to determine the end of infusion point – this could disclose information about the reservoir as to its capacity (see column 8, lines 33-43).

With respect to claim 10, the modified Shearn does not explicitly disclose the use of a substantially uniform light source, but such would have been obvious to one of ordinary skill in the art because this would prevent false readings of the sensor from occurring.

With respect to claim 11, the modified Shearn does not explicitly disclose the repetition of encoding features, but such would have been obvious to one of ordinary skill in order to allow for increased range of displacement detection.

With respect to claim 20, the modified Shearn does not explicitly include the step of storing each successive detector array value in each of successive groups, but such would have been obvious to modify the modified Shearn accordingly in order to accurately determine the rate of displacement to calculate a volumetric flow rate out of the syringe.

Response to Arguments

5. Applicant's arguments filed 12/12/2005 have been fully considered but they are not persuasive.

The main thrust of applicant's arguments appears to be that the device disclosed by Shearn only discloses the determination of the near-end-of-infusion point. However, the marks (58) illustrated in figure 6 show that there are different sized marks on the plunger depending on the amount of volume left. Because the marks are of different sizes, it would be obvious to one of ordinary skill in the art to determine the position of the plunger, as there would be a different signal resulting for all positions of the plunger. The positional aspect is also incorporated by the fact that the device taught by Shearn

monitors the rate at which the plunger outputs the liquid (see column 8, lines 1-5 & 22-26). As a result, the rejection is maintained.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick J. Lee whose telephone number is (571) 272-2440. The examiner can normally be reached on Monday through Friday, 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Georgia Epps can be reached on (571) 272-2328. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick J. Lee
Examiner
Art Unit 2878

PJL
January 3, 2006


Stephone B. Allen
Primary Examiner